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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/664,485 | 09/18/2000 | Ilya Trakht | 55099-A-PCT-US/JPW/GJC | 4698 |

7590 08/09/2006
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, NY 10036

EXAMINER

KINSEY, NICOLE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant No.

09/664,485

Applicant(s)

TRAKHT, ILYA

Examiner

Nicole E. Kinsey, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Priority Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 79-110 is/are pending in the application.
- 4a) Of the above claim(s) 83-88, 97, 99, 100 and 102-105 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 79-82, 89-96, 98, 101 and 106-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/13/04 & 1/21/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to for the following:

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 107 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 107 is vague and indefinite since one cannot determine that which is intended by the recitation of "B6B11-like cell" since B6B11 is a specific heteromyeloma cell deposited under accession No. HB-12481.

Applicant argues that claims must be read in light of the specification and that "B6B11-like" is defined in the specification (page 23, lines 29-31). This definition states that a "B6B11-like" cell is a hybrid cell produced by the fusion of mouse myeloma 653-related cell and human myeloma RPMI 8226-related cell. This definition does not render the term "B6B11-like" definite because, for example, the definition term "related" (e.g., mouse myeloma 653-related cell and human myeloma RPMI 8226-related cell) is not defined by the claim or specification. Further, the specification does not provide a standard for ascertaining the requisite degree of "relatedness" between a particular cell and a mouse myeloma 653-related cell or a human myeloma RPMI 8226-related cell. Therefore, one of ordinary skill in the art would not be able to determine whether or not a particular cell is "related" to a mouse myeloma 653 cell or a human myeloma RPMI 8226 cell.

The phrase "B6B11-like cell" renders the claim(s) indefinite because the claim includes elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim unascertainable. One of ordinary skill in the art would not be able to determine the required degree of "likeness" between a particular cell and a B6B11 cell to know whether he/she is within the metes and bounds of the claim.

Applicant further argues that "B6B11-like" cells share functional properties and characteristics with B6B11 heteromyeloma cells. However, the specification does not teach which and how many of these functions and properties are necessary to render a cell "B6B-like."

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 and § 103 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

102 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

103 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 79-82, 89-92 and 106-110 are product-by-process claims, which are drawn to a composition comprising a suitable carrier and an effective amount of a monoclonal antibody. The method steps recited to produce the monoclonal antibody are not considered when determining patentability of the product (MPEP § 2113). In *In re Thorpe*, the court stated, "even though product-by-process claims are limited by and

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defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 79-82, 89-92 and 106-110 are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Rosok et al. (U.S. Patent No. 4,834,976).

Rosok et al. discloses compositions of monoclonal antibodies and carriers (see col. 4, line 22-38; col. 8, line 9 to col. 9, line 27; the examples; and the claims). Given the claim is drawn to a composition comprising a suitable carrier and an effective amount of a monoclonal antibody, the compositions disclosed in Rosok et al. meet the limitations of the instant product-by-process claims. Where applicant claims a composition in terms of a characteristic not explicitly disclosed by the reference, a 102/103 rejection is proper (MPEP 2113).

Claims 79-82, 89-96, 98, 101 and 106-110 are rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Chu et al. (U.S. Patent No. 5,652,114).

Chu et al. discloses a composition of monoclonal antibodies and a carrier (see col. 13, lines 18-22 and col. 15, line 64 to col. 16, line 3). Given the claim is drawn to a

composition comprising a suitable carrier and an effective amount of a monoclonal antibody, the compositions disclosed in Chu et al. meet the limitations of the instant product-by-process claims. Where applicant claims a composition in terms of a characteristic not explicitly disclosed by the reference, a 102/103 rejection is proper (MPEP 2113).

In addition, Chu et. al. describes methods for treating/preventing a condition (e.g., breast cancer and tumors) by administering to a subject an amount of a composition of monoclonal antibodies in a carrier effective to bind the antigen associated with the condition so as to treat/prevent the condition (see col. 6, lines 57-59; col. 7, lines 5-8; col. 13, lines 10-27; col. 42, line 50 to col. 44, line 43).

No claim is allowed.

Conclusion

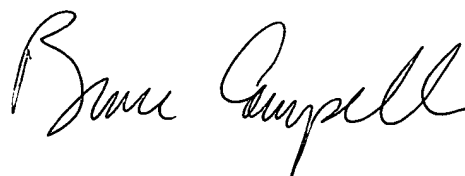
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached Monday through Friday 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Bruce Campell". The signature is fluid and cursive, with the first name "Bruce" and last name "Campell" clearly distinguishable.

**BRUCE R. CAMPPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600**